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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/041,491 03/12/98 SCHWABE

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EXAMINER

NM12/0307

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NEW YORK NY 10036-2711

GUPTA, A

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

03/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



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EXAMINER

ART UNIT	PAPER NUMBER
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Below is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

DATE MAILED:

ADVISORY ACTION

■ THE PERIOD FOR RESPONSE

- a) ☐ is extended to run __ or continues to run __ from the date of the final rejection.
b) ☐ expires three months from the date of the final rejection or as to the mailing date of this Advisory Action, whichever is later.
In no event however, will the statutory period for response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response as set forth in b) above.

- Appellant's Brief is due in accordance with 37 CFR 1.192(a).
■ Applicant's response to the final rejection, filed 1-27-00, has been considered with the following effect, but is not deemed to place the case in condition for allowance.
1. ■ The proposed amendments to the claim/and or specification will not be entered and the final rejection stands because:
- a. ■ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
 - b. ■ They raise new issues that would require further consideration and/or search. (See note).
 - c. ☐ They raise the issue of new matter (See note).
 - d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
 - e. ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
- NOTE: The amendment to claim 15 would raise a 112 Second paragraph.

2. ☐ Newly proposed or amended claims __ would be allowed if submitted in a separately filed amendment canceling the non-allowable claims.
3. ■ Upon the filing of an appeal, the proposed amendment ☐ will be entered ■ will not be entered and the status of the claims will be as follows:

Claims allowed: None
Claims objected to: None
Claims rejected: 4-6 and 14-20

However;

- ☐ Applicant's response has overcome the following rejection(s): None

4. ☒ The affidavit, exhibit or request for reconsideration has been considered, but does not overcome the rejection because Rejection under 112 First Paragraph is maintained for the reasons set forth in the Previous office actions and the reasons set forth below.

Applicants argue that the functional similarities between relaxin like factor and relaxin is a basis of the invention and one of many bases for the treatment of disease with relaxin like factor recited in claims 4-6 and 14-16. Furthermore, the synergistic effects of relaxin like factor on relaxin in vitro and in vivo enables one of ordinary skill in the art to recognize that any conditions susceptible to treatment with relaxin can show a synergistic response to simultaneous treatment. Applicants exemplifying various treatments with relaxin and conclude that due to the functional relationship between relaxin and relaxin like factor, one would expect relaxin like factor to treat such disorders.

Applicants also state that the specification is fully enabled for the full scope of the claims since the claims are drawn to the treatment of a condition susceptible to treatment with relaxin. "[O]ne of ordinary skill in the art could determine conditions susceptible to treatment with relaxin like factor based on those conditions that are susceptible to treatment with relaxin in the course of ordinary experimentation."

Finally, for correlation from in vitro to in vivo efficacy, Applicants make reference to the fact that relaxin like factor binds to the relaxin receptor and therefore the activities cited in the art for relaxin would also correlate to relaxin like factor. Accordingly, the in vivo methods cited for relaxin would correlate to relaxin like factor.

Applicant's arguments filed 1-27-00 have been fully considered but they are not persuasive.

Applicants arguments are based on the fact that since relaxin like factor recognizes the same receptor as relaxin and there are functional similarities in some activities, one of ordinary skill in the art could extrapolate the activities associated with relaxin to relaxin like factor. Although there may be some similarity between activities of relaxin and relaxin like factor, a correlation between all activities attributed with relaxin to relaxin like factor cannot be made without undue experimentation. The art has recognized various drugs that, while in one instance have similar activity, in another instance they completely different activity. For example, in the treatment of cardiovascular disorders such as arrhythmia, drugs such as Lidocaine and Mexiletine can have different effects. Lidocaine is effective in treating Ventricular fibrillation, while Mexiletine is not. On the other hand, Mexiletine is effective in treating Ventricular arrhythmias in cardiomyopathy and Ventricular tachycardia while Lidocaine is not. It is known in the art that Lidocaine has substantial first pass hepatic metabolism, while Mexiletine, an analog of Lidocaine with similar electrophysiologic actions but has little or no first pass hepatic metabolism. Therefore, one of ordinary skill in the art cannot reasonably extrapolate that since two compound exhibit similar activities in certain respects will exhibit similar activities in all respects.

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

